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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/404,010	09/23/1999	YING LUO	A-68294/DJB/	7948

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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/404,010

Applicant(s)

LUO ET AL.

Examiner

Janet L. Andres

Art Unit

1646

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 February 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on 22 February 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 25-33.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: The rejection of claims 25-33 under 35 U.S.C. 101 as lacking utility is not overcome by Applicant's arguments or the declaration of Dr. Hitoshi.

Dr. Hitoshi states that one of skill in the art would believe that Mkinase "has a role" in tumorigenesis and signal transduction. Dr. Hitoshi further states that, based on Kato and on the comparison of NTKL and Mkinase, it is more likely than not that the Mkinase gene is useful as a diagnostic for cancer. Dr. Hitoshi concludes that one of skill would believe that the Mkinase protein was involved in tumorigenesis.

The declaration of Dr. Hitoshi has been fully considered but fails to overcome the rejection. The mere statement that Mkinase is somehow "involved" in cell cycling and tumorigenesis fails to provide any guidance as to how it is involved. Based on Applicant's teachings, the artisan would only know that it bound to TRAF4. The artisan would not be able to tell whether it was active during the cell cycle or served as an inhibitor of the cell cycle. Furthermore, the artisan would not be able, based on Applicant's specification, to diagnose any cancer. Applicant provides only the suggestion that it can be used to diagnose cancer but no information as to what cancer or cancers could be diagnosed and whether, for example, Mkinase levels would be decreased or increased. The teachings of Kato provide evidence that the protein might be a useful tool for cancer diagnosis. However, Applicant's specification provides no guidance to indicate that the gene was located near a breakpoint. Again, all that is provided are general assertions.

Applicant argues that it was stated that cancer is not a specific disease, and provided a definition of cancer. Applicant argues that disclosure of the diagnostic use of Mkinase is found in the specification. Applicant points again to the declaration of Dr. Hitoshi. Applicant states that TRAF4 is differentially expressed.

Applicant's arguments have been fully considered but have not been found to be persuasive. As was stated in the previous office action, "cancer" is in fact many diseases with many causes. The specification does not teach how Mkinase could be used to diagnose any cancer. All that is disclosed is that the protein binds TRAF4. What is provided are art-standard methods by which the artisan could experiment to find out whether, and how, Mkinase could be used to diagnose a cancer. This is merely an invitation to the artisan to experiment to find out whether Mkinase could be used to identify a disease state.

The rejection of claims 25-33 under 35 U.S.C. 112, first paragraph, as lacking enablement because the invention lacks utility is not overcome by Applicant's arguments or the declaration of Dr. Hitoshi.

Applicant argues that Mkinase has utility and thus this rejection should be withdrawn. Since, for the reasons stated above, Applicant's arguments have not been found to be persuasive, the rejection is maintained.


JANET ANDRIES
PRIMARY EXAMINER